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# December 14, 2006

**Exhibits: Note: only REVISED Exhibits are submitted with the December 14, 2006 Application. All other Exhibits (not revised) were previously submitted with the March 1, 2001 Application and are not included in this December 14, 2006 renewal application at the request of NC-DENR Solid Waste Section.**

## I. Permits for Solid Waste Management Facilities

A. Permit Application

**Note: this is the 5-28-10 version of the December 14, 2006 Renewal Application for Solid Waste Permit No. 32-09-I, originally issued February 8, 1996 and renewed May 14, 2002. Current permit approved March 22, 2007.**

General Facility Description

The following information describes the GlaxoSmithKline South Campus, a pharmaceutical research and development facility located at 3030 Cornwallis Road, Research Triangle Park (RTP), North Carolina 27709. The Company's location consists of land parcels on both sides of Cornwallis Road. The Main Complex and South Complex are adjacent to each other on the south side of Cornwallis Road. The North Complex is located opposite the Main Complex on the north side of Cornwallis Road. GlaxoSmithKline also leases space in Research Commons II, which is located adjacent to the South Complex on geographically contiguous property.

The Main Complex contains administrative offices, and research laboratories. The Main Building Medical Waste incinerator ID No. 42938 (Permit 32-08-I) has been closed and has been removed from this permit. The South Complex contains only administrative offices. The North Complex contains administrative and research laboratories; and the Environmental Complex consisting of two (2) Hazardous Waste Storage Areas, a warehouse, and the P-bldg Solid Waste Incineration Facility ID No. MWI-2. GlaxoSmithKline leases space for administrative offices and research laboratories in Research Commons II but will vacate the facility in 2007. Exhibit #5 is a site plan for the GlaxoSmithKline, RTP facility that shows the location of buildings at the Main complex, South Complex and North Complex.

Solid wastes generated throughout the campus as a result of administrative, maintenance, and pharmaceutical research and development activities are collected and managed based on the activity generating the waste and the composition of the waste. Section IV provides a description of the waste types, generation locations, projected volumes and methods of waste management for transport and disposal.

GlaxoSmithKline South Campus will also be receiving wastes from other US facilities operated by GlaxoSmithKline's parent company, GlaxoSmithKline plc. Wastes received from off site facilities will be similar in composition to the wastes generated on the GlaxoSmithKline RTP site. The wastes from offsite facilities will be collected and shipped by a licensed waste transporter to the GlaxoSmithKline South Campus Environmental Complex Incinerator ID No. MWI-2 for incineration with like wastes or for consolidation and transport to an approved off site disposal facility.

The GlaxoSmithKline sites in NC include:

| FACILITY | EPA ID NUMBER | LOCATION |
|---|---|---|
| GlaxoSmithKline South (Cornwallis Rd) Campus | NCD052547635 | RTP, NC |
| GlaxoSmithKline North (5 Moore Drive) Campus | NCD065655599 | RTP, NC |
| GlaxoSmithKline Imperial Center Campus | NCD982117384 | Morrisville, NC |
| GlaxoSmithKline Central Distribution Center and Promomotional Distribution Center - Closed 2010 | N/A | Durham, NC |
| GlaxoSmithKline TriCenter Central Receiving | N/A | Durham, NC |

| | | |
|---|---|---|
| GlaxoSmithKline Zebulon Facility | NCD101740215 | Zebulon, NC |
| Stiefel Labs, a GlaxoSmithKline company | NCR000009662 | RTP, NC |

Exhibit # 1, is a topographic map showing the relationship of GlaxoSmithKline South Campus (circled) to Durham County, North Carolina. The map scale is 1 inch equals 2000 feet. The contour interval of elevation is 10 feet. Exhibit # 1 shows the surrounding land use beyond the boundary of GlaxoSmithKline South Campus. The circled portion encompasses an area in excess of 1000 feet from the GlaxoSmithKline South Campus property line. There is no residential property within 1000 feet of the GlaxoSmithKline, RTP facility. The Research Triangle Park is a wooded area of approximately 5000 acres occupied by business, commercial, research and government tenants.

Exhibits # 2, # 3, and # 4 are plot plans of the North Complex showing the facility boundaries, three (3) Hazardous Waste Storage Areas, Solid Waste incinerator building and selected details. Note that Hazardous Waste Storage Area #3 has been closed. The map scale is 1 inch equals 100 feet.

Exhibits # 5, # 6, # 7 and # 8 are topographic maps with a scale of 1 inch = 200 feet and a contour interval of 2 feet which address surface waters and surrounding land use at a distance of 1000 feet around the North Complex. The loading and unloading areas are shown in Exhibits # 8, # 9 and # 10.

The North Complex incinerator is a Consumat Systems, Inc. 2,000 pound per hour model CS-7602 incinerator with a model ML-561 loader, model AR-4284 ash conveyor, and a 96" outer diameter quench chamber. The system descriptions are in the plans and specifications Exhibit # 13.

(1) Site and Construction Plans (15A NCAC 13B.0202(1))

Exhibits # 9 and # 10 show access and internal roads and buildings at the Main Complex, South Complex and North Complex. The Main Complex and South Complex are located on geographically contiguous property on the south side of Cornwallis Road. The North Complex is located opposite the Main Complex on the north side of Cornwallis Road.

(2) Zoning Approval (15A NCAC 13B.0202(2))

Exhibit # 11 is a letter from the zoning authority indicating that the facility meets the local zoning ordinance. In addition Exhibit # 12 is a letter from the Research Triangle Foundation Board of Design approving the incineration site plans.

(3) Site Plans and Specifications (15A NCAC 13B.0202(3))

Exhibit # 13 contains copies of the plans and specifications for the MWI-2 facility.

## II. Treatment and Processing Facilities (15A NCAC 13B.0301)

A. Application Requirements for Treatment and Processing Facilities (15A NCAC 13B.0301)

(1) Operations Plan (15A NCAC 13B.0301)(1)

Exhibits # 9 and # 10 are site plans for the GlaxoSmithKline Facility.

Operations plans for the MWI-2 are described in Exhibit #21 Operations and Maintenance manuals.

(2) Zoning Authority (15A NCAC 13B.0301)(2)

Exhibit # 11 is a letter from the zoning authority indicating that the facility meets the local zoning ordinance. In addition Exhibit # 12 is a letter from the Research Triangle Foundation Board of Design approving the incineration site plans.

(3) Plans and Specifications (15A NCAC 13B.0301)(3)

Exhibit # 13 contains copies of the plans and specifications for the North Complex incineration facility.

B. Operational Requirements (15A NCAC 13B.0302)

(1) Permitted Waste Types (15A NCAC 13B.0302)(2)

Environmental Complex Incinerator ID No. MWI-2 is permitted to receive types 0, 1, 2, 3, 4, 5, and 6.

(2) Disposition of water that has contacted Solid Waste (15A NCAC 13B.0302)(3)

(a) All management of Solid Waste at the MWI-2 disposal facility takes place inside of the building.

Water that has been delivered to the Environmental Complex waste incinerator MWI-2 as a result of accumulation in a roll-off or compactor, as well as, water that is resultant from cleaning solid waste handling areas is discharged to a sanitary sewer drain.

GlaxoSmithKline has a Storm Water Discharge Permit No. NCG060000 Certificate of Coverage No. NCG060107. The North Complex and South Complex are authorized to discharge wastewater under Industrial Waste Discharge Permit No. DC-10.

(b) <u>Overfire Water Tank system</u>
The incinerator uses domestic water injected into the primary (lower) combustion chamber to cool the burning waste when the temperature exceeds 1500 F. In 2009 a project was completed that provides a tank and pump system to allow reclaimed wastewater to be substituted for the domestic cooling water. This is known as the Overfire Water Tank system. The reclaimed (Disso) water is unregulated aqueous wastewater containing dilute concentrations of pharmaceutical compounds from R&D operations. Now, either domestic water or unregulated wastewater can be used for cooling with this system. Drums of approved Disso wastewater are periodically pumped into the Overfire Water tank system, per the approved GSK SOP.

The Overfire Tank water injected into the incinerator immediately evaporates to provide process cooling. The trace pharmaceutical constituents in the Overfire Tank water are incinerated in the upper chambers and are destroyed. It is not likely that any residues from the Overfire Tank wastewater are present in either

the incinerator ash or in the bag-house spent lime.

The Overfire Water Tank system includes the following components:

- 800 gallon polypropylene tank with agitator and level sensors.
- Feed pump to deliver cooling water to the incinerator.
- Automated control valve to select either domestic water or tank water.
- Control Panel to control the agitator, control valve, and feed pump based on the level of the tank.
- Inlet pump with filter system to pump water from drums into the tank.
- Interconnecting piping.

Refer to Exhibit 19 for the P-Building Overfire Water Tank Operations Instructions. The incinerator staff will receive regular training on the requirements of the SOP according to GSK policy. Initial training was completed on 2/26/2010.

(3) Fire Protection Equipment (15A NCAC 13B.0302)(4)

The Environmental Complex incinerator is equipped with a sprinkler system. Exhibit # 17 depicts the fire control equipment for the Environmental Complex.

(4) Vector Control Measures (15A NCAC 13B.0302)(5)

GlaxoSmithKline incineration facilities are serviced periodically as needed by a licensed pest control company for control of vermin, insects, flies and other insects.

(5) Sanitation Maintenance and Equipment (15A NCAC 13B.0302)(6)

The Environmental Complex waste handling floor has floor drains and is coated with epoxy flooring to facilitate cleaning. The typical operations will include handling waste materials both in boxes as well as from dumpster or compactor dumping on the facility floor. Carts and pallets will be used to transfer the wastes from the facility floor and load into the incinerator charging area. Water from the floor wash will be sent to a sanitary sewer.

Cleaning equipment includes: mops, buckets, disinfectant soap, hoses and squeegees to clean the facility. Facility staff will wear appropriate personal protective equipment to perform cleaning operations.

(6) Windblown Materials (15A NCAC 13B.0302)(7)

All solid waste management activities are conducted inside of a building for protection from the elements. Wind does not contribute to dispersion of materials. The premises are routinely patrolled to collect materials that may have been released during transport of bulk containers to the facilities.

## III. Disposal Sites (15A NCAC 13B.0500)

A. Siting Requirements for Disposal Sites (15A NCAC 13B.0503)

(1)(a). Exhibit # 18 is the Flood Insurance Rate Map as provided by the U.S. Department of Housing and Urban Development Federal Insurance Administration for the RTP area. The map indicates that the GlaxoSmithKline facility is not within the 100 yr.

floodplain.

(1)(b)(i) There are no designated areas of endangered or protected species on the GlaxoSmithKline South Campus site.

(ii) There are no designated critical habitat of endangered or threatened species on the GlaxoSmithKline site.

(iii) There are no known archeological or historical sites on the GlaxoSmithKline site.

(iv) The National Historic Preservation Act of 1966 is not applicable since issuance of a Solid Waste Permit will not create potential adverse effects of the licensed activities and properties listed or eligible for listing in the National Register of Historic Places.

(2)(b) Site Access (15A NCAC 13B.0503(2)(b))

Exhibit # 3 depicts the Environmental Complex security systems.

(2)(f) Buffer Zone from the disposal area to:

(i) 50-foot to the property line; and

(ii) 500-foot to private dwellings and wells;

The GlaxoSmithKline Facility is located in the Research Triangle Park (RTP), a 5,000 acre industrial park including business, research, commercial and government tenants.

(iii) 50-foot to rivers or streams

Exhibits # 9, # 10, # 2 and # 20 are topographical maps with a scale of 1 inch = 200 ft and a contour interval of 2 feet which address the surface waters and surrounding land use at a distance of 1000 feet.

## IV. Application Requirements for incinerators (15A NCAC 13B.0508)

(1) Site and operations plans (15A NCAC 13B.0508(1))

Exhibits # 9 and # 10 show access and internal roads and buildings at the Main Complex, South Complex and North Complex.

Exhibit # 21 is the Operations manual for the North Complex incinerator ID No. MWI-2.

(2) Air Quality Permit (15A NCAC 13B.0508(2))

Exhibit # 22 is a copy of the NC Division of Air Quality Air Permit Number 4612T25 for the GlaxoSmithKline RTP facilities. The incinerator is subject to the 40 CFR Part 62 requirements for Commercial and Industrial Solid Waste Incinerators (CISWI rule).

(3) Zoning Authority (15A NCAC 13B.0508(3))

Exhibit # 11 is a letter from the zoning authority indicating that the facility meets the local zoning ordinance. In addition Exhibit # 12 is a letter from the Research Triangle Foundation Board of Design approving the incineration site plans.

(4) The type, quantity and source of waste for disposal. (15A NCAC 13B.0508(4))

(a)(1) Waste Types

| Waste Code | Principal components, usual sources and typical moisture content | Estimated Quantity Generated Onsite (lb/yr) | Estimated Quantity Received from Offsite (lb/yr) |
|---|---|---|---|
| **0** | Highly combustible waste, paper, wood, cardboard cartons, including up to 10 % treated papers, plastic or rubber scraps, bio-waste, medical waste, low level radioactive waste, sharps, lab trash; containing a to 10% moisture. | **2,000,000** | **2,000,000** |
| **1** | Combustible waste, paper, cartons, rags, wood, scraps, combustible floor sweepings; animal bedding, bio-waste, medical waste, low level radioactive waste, containing a to 25 % moisture. | **1,400,000** | **1,300,000** |
| **2** | Rubbish and garbage; 50 % moisture. (ex. cafeteria wastes, general trash) | **200,000** | **150,000** |
| **3** | Predominantly animal and vegetable waste; 70 % moisture. (ex. cafeteria wastes) | **180,000** | **150,000** |
| **4** | Carcasses, organs, solid organic wastes from hospitals, laboratories and similar sources; 85 %o moisture. | **150,000** | **100,000** |
| **5** | Gaseous and semi-liquid industrial process waste; variable moisture. | **20,000** | |
| **6** | Solid and semi-solid by-product waste, such as rubber, plastics, wood wastes, etc., from industrial operations; variable moisture. | **50,000** | **50,000** |
| | | | |
| | **Total Waste Volume (estimated)** | **4,000,000** | **3,770,000** |
| | **Percent of Total** | **51%** | **49%** |
| | | | |
| | **Total Waste Volume Available for Incineration from Onsite and Offsite Locations** | **7,770,000 lbs** | |
| | | | |
| | **Maximum Incineration Capacity MWI-2** | **17,520,000 lbs** | |

Specific examples of wastes generated onsite or received from offsite are animal bedding contained with animal wastes, carcasses, tissues and organs, sharps, biohazard wastes, pharmaceutical returns, non-hazardous chemicals and low level radioactive wastes.

(a)(2) Waste Screening and Certification

Purpose: Ensure all materials fed to the P-bldg MWI-2 solid waste incinerator are subjected to a screening process to determine if they are suitable for the

incinerator, are approved for incineration, and are certified as approved for each load of ash and lime.

The Waste Screening and Certification Process is as follows:

(i) The P-Bldg Products Master List includes all GSK products and materials that may be submitted for disposal. Each product or material is screened for acceptability for the P-bldg MWI-2 solid waste incinerator and documented on the Master List. GSK Prescribing Information or MSDS data are used to identify constituents. Hazardous and Radioactive constituents are not accepted at the incinerator. The Master List is updated with each new product screened and is reviewed semi-annually. Refer to Exhibit 14 for the initial P-Bldg Products Master List – Note: this is GSK company confidential information.

(ii) The Daily Burn List form documents that each product or material is approved to burn. Refer to Exhibit 15 for the Daily Burn List form. The P-bldg Product Master List is checked for each product or material before incineration to verify if approved for incineration. Each product or material is documented on the Daily Burn List form for each burn day. The operator initials each form entry to verify that each product or material is approved. Management screens any/all products or materials not on the P-bldg Product Master List before approving for the incinerator. The Daily Burn List documents when the Overfire (Disso) Water Tank is in service and verifies that all Disso wastewater drums on the Disso log are approved. The Disso tank process has its own SOP that documents the review and approval process for each drum of Disso wastewater. Refer to Exhibit 19 for the P-Building Overfire Water Tank Operations Instructions. The completed Daily Burn List is attached to the Daily Burn Log and stored in the Burn Log binder.

(iii) The Screening Certification Log is completed for each ash container (e.g. CS-099 Box-1) and spent lime container (e.g. LS-077 Box-11) before shipment. Refer to Exhibit 16 for the Screening Certification Log. Before shipment, the Screening Certification Log form is reviewed and signed by the incinerator manager certifying that the ash/lime container is for the specified burn days and that each burn day has a completed Daily Burn List with all items approved. The Screening Certification Log is attached to the GSK copy of the WM outgoing shipping manifest for each ash and lime shipment and stored with the MW shipping records.

(b) Waste Volumes and Projected Volumes

The following is a brief description of these wastes and projected volumes available for incineration at the GlaxoSmithKline incinerator ID No. MWI-2 .

(b)(1) Animal Bedding

Animal bedding contaminated with animal wastes are included in category 0 or 1 wastes and are generated at approximately 625,000 pounds per year at the GlaxoSmithKline and an additional 625,000 pounds per year may be received from offsite facilities. These wastes are either accumulated in trash compactors or are bagged and boxed for shipment to the incinerator. Trash compactors or other trash containers will be picked up from generating locations routinely based on generation rates and transported to Incinerator MWI-2 by either a contracted

service or qualified site personnel. At MWI-2 wastes will be dumped onto the incineration facility floor for processing into the incinerator.

(b)(2) Carcasses

Carcasses and biological tissue samples are included in the category 4 wastes and contribute approximately 150,000 lbs per of waste per year from the GlaxoSmithKline facilities for incineration. An additional 100,000 pounds of carcasses and biological tissues may be received from offsite locations.

Carcasses and tissues will be packaged in 3 mil. plastic 165 gram dropped dart test bags or plastic bags and approved fiberboard or plastic containers. Containers of regulated medical wastes received from offsite will be packaged and labeled at the generators' site according to 15A NCAC 13B.1204. Transportation of regulated medical wastes will be documented according to 15A NCAC 13B.1205. Carcasses and tissues that are not regulated medical wastes will be packaged using the same criteria for receipt at the GlaxoSmithKline incineration for disposal.

(b)(3) Medical Waste

Medical wastes as defined in G.S. 130A-290.18 including: sharps, blood or body fluids, pathological and microbiological wastes that are known to have been exposed to or contain biological agents above Biological Safety Level III must be autoclaved or otherwise treated to remove the infectious agent prior to disposal by incineration. These wastes are packaged for transportation in plastic bags inside of fiberboard or plastic containers which in combination meet 15A NCAC 13B.1204(a)(1) requirements. Refer to Exhibit #23, Medical Waste Management Plan.

Approximately 50,000 pounds of medical wastes are generated at the GlaxoSmithKline site each year and an additional 50,000 pounds per year may be received from offsite generators. The waste is generally categorized as type 0 or 1 waste.

(b)(4) Bio-waste

Bio wastes are type 0 or 1 wastes consisting of paper, plastic, rubber, glass, sharps, etc. and other materials that were generated as a result of research or related activities where biological agents have been used. Any material having been exposed to or suspected to have been exposed to biological as a result of research involving biological agents is included in this general category of wastes. These wastes are packaged for transportation in plastic bags for local transport and plastic bags inside of fiberboard or plastic containers which in combination meet 15A NCAC 13B.1204(a)(1) requirements.

Approximately 180,000 pounds of bio-wastes are generated on the GlaxoSmithKline site each year and an additional 150,000 pounds of bio-wastes may be received from offsite generators.

(b)(5) Pharmaceutical Returns and Rejects

Pharmaceutical rejects and returns consist of non-hazardous pharmaceutical

products, paper, cardboard and plastic packaging and excipients used in pharmaceutical manufacturing at GlaxoSmithKline facilities. Rejects consist of pharmaceutical products, excipients and contaminated paper, cardboard and plastic materials resulting from products not meeting QA/QA criteria, manufacturing testing or from out of date stocks. Pharmaceutical returns are GlaxoSmithKline products and packaging materials returned to the facility as a result of clinical trials, damaged goods or out of date shelf stocks. This type waste also includes consumer healthcare products that are similar in constituents to the above described pharmaceutical materials.

Approximately 1,000,000 pounds of pharmaceutical rejects and returns are generated on the GlaxoSmithKline site each year and an additional 1,000,000 pounds of pharmaceutical rejects and returns may be received from offsite generators.

(b)(6) Low Level Radioactive Wastes

Low level radioactive wastes are type 0 and 1 wastes consisting primarily of paper, plastic, cardboard, gloves, bench covers and protective garments such as tyvek suits. The approximate volume is 20,000 pounds per year generated from the GlaxoSmithKline and an additional 20,000 pounds per year received from offsite facilities. Note: this waste is from decayed radioactive material that is no longer regulated as radioactive by the NC Radiation Protection Division standards.

(b)(7) Trash

Types 0 through 6 generated from general site operations may consist of the following:

| | | |
|---|---|---|
| wooden pallets | lab clothing/gloves | computer paper |
| cardboard | clear/green glass | tin or aluminum cans |
| HDPE containers | Styrofoam | borosilicate glass |
| milk cartons | animal bedding | food waste |
| wood | wet towels | broken glass/plastic |
| lab wrappers/plastic | feed bags | shrink wrap |
| glass pipettes | wire | fiberglass filters |
| paper - food grade | china/silverware | aluminum foil |
| polystyrene containers | plastic strapping | contaminated mixed paper |

The main focus of GlaxoSmithKline will be to take advantage of recycling, reuse or reduction opportunities for the above wastes. However, in the event that these wastes cannot be recycled or reused GlaxoSmithKline will use onsite management via incineration.

## V. Operational Requirements for Incinerators (15A NCAC 13B.0509)

(1) Designed and Operated to prevent nuisance or potential health hazard (15A NCAC 13B.0509(l))

Exhibit # 21 contains the design and operations specifications for the MWI-2. The operations and maintenance procedures are also included.

(2) Minimizing interference with other area activities (15A NCAC 13B.0509(2))

As noted in the land use exhibits # 5, # 6, # 7 and # 8, the facilities are located within the GlaxoSmithKline campus and do not contribute to interference with activities onsite or offsite.

(3) Storage and Dumping Areas (15A NCAC 13B.0509(3))

Waste received at the Environmental Complex incinerator MWI-2 will be placed on the tipping floor of the facility or in adjacent Warehouse B. As noted on the facility diagrams there is an area provided for the storage of Low Level Radioactive wastes during decay. Ash generated from incineration will be stored in designated areas on the lower level in roll-offs or dump bins.

(4) Vector Control (15A NCAC 13B.0509(4))

GlaxoSmithKline incineration facilities are serviced periodically as needed by a licensed pest control company for control of vermin, insects, flies and other insects.

(5) Sanitation Maintenance and Equipment (15A NCAC 13B.0509(5))

Equipment and tools are provided in the storage and charging areas to maintain the facility in a sanitary condition. See (15A NCAC 13B.0302)(6)

(6) Disposal of incinerator plant residue. (15A NCAC 13B.0509(6))

Ash and residues generated from operations at the facility will be collected into roll-off containers or compactors for disposal at an approved sanitary landfill. Containers will be removed by a contract waste hauler when filled or during extended interruptions in operations.

(7) Air Quality Permit (15A NCAC 13B.0509(7))

Exhibit # 22 is a copy of the NC Division of Air Quality Air Permit Number 4612T25 for the GlaxoSmithKline South Campus. The incinerator is subject to the 40 CFR Part 62 requirements for Commercial and Industrial Solid Waste Incinerators (CISWI rule).

(8) Waste Receiving (15A NCAC 13B.0509(8))

Waste management technicians and operators assure that only those solid wastes permitted for receipt at the facilities will be incinerated. Personnel training and visual inspections of the waste on the dumping floor will provide adequate opportunity to identify and exclude non-permitted wastes. Waste received in containers or from offsite is labeled to indicate the contents.

(9) Disposition of water that has contacted Solid Waste (15A NCAC 13B.0509(9))

GlaxoSmithKline incineration facilities are inside of buildings and all management of Solid Waste at the disposal facilities take place inside of buildings.

Water that has been delivered to the Environmental Complex waste incinerator as

a result of accumulation in a roll-off or compactor, as well as water that is resultant from cleaning solid waste handling areas is discharged to a sanitary sewer drain.

The GlaxoSmithKline- has a Storm Water Discharge Permit No. NCG060000 and Certificate of Coverage No. NCG060107. The Environmental Complex is authorized to discharge wastewater under Industrial Waste Discharge Permit No. DC- 010.

**VI. Medical Waste Management (15A NCAC 13B.1207) Note: 1. This section was updated in July 2007 to reflect agreements with the NC Solid Waste Section concerning the ASH SAMPLING PLAN. Note 2. This section was revised in July 2009 to reflect updated agreements with the NC Solid Waste Section and Republic Services UPE landfill staff concerning the ASH SAMPLING PLAN.**

1) Exhibit # 23 describes the practices and procedures for management of Medical Waste at the GlaxoSmithKline facility and at offsite generators that may be transporting wastes to the incineration facilities.

2) **ASH SAMPLING PLAN:** Operational Requirements/Regulated Medical Waste Treatment Facilities (15A NCAC 13B.1207) Sections (3)(f) through (k) - Ash Sampling Plan for Medical Waste Incineration System MWI-2.

The MWI-2 incineration unit consists of a Consumat 2,000 pound per hour multiple chambered medical waste incinerator permitted for types 0,1, 2, 3, 4, 5, and 6 wastes. The incinerator is attached to an Interel baghouse filter Permit Id. No. BF-1 for removal of particulates and reduction of acid gasses.

Treatment residues generated from the incineration process consist of:

A. Bottom Ash from incinerated materials - generated at the ash retrieval system on the lower combustion chamber, and
B. Off-gas treatment residues (spent lime) and fly-ash - generated at the Air Pollution Control System.

A. Bottom ash, here-after known as “ash”, is removed from the incinerator using a wet retrieval ash conveyor. Ash is pushed from the secondary hearth of the primary chamber into a water filled receiving sump for quenching. The ash is removed from the sump by a chain drag which drags portions of the ash up a ramp for de-watering. Wetting the ash quenches any burning materials and also prevents the formation of dust. Ash is collected in small hoppers (1 to 2 yards) allowing the ash to further de-water. Hoppers are then combined into a large roll-off container (10 to 20 yards). During the scheduled sampling period, each hopper destined for the sample roll-off is sampled per the GSK sampling procedure, thereby creating a representative sample of the filled ash roll-off. The composite ash sample is analyzed and, if approved by the landfill, is released for disposal. An approved waste hauling company is contracted to haul the ash to an approved landfill for disposal

B. Off-gas treatment residues (spent lime) and fly-ash, here-after known as “spent lime”, is generated as a result of off-gas treatment with hydrated lime. The spent lime is filtered and collected in the bag-house. A screw conveyor moves the spent lime to an enclosed roll-off container. The enclosed conveyors, enclosed roll-off container, and associated dust collector prevent the dissipation of dust. During the scheduled sampling period, periodic samples are extracted from the spent lime conveyor per the GSK sampling

procedure, thereby creating a representative sample of the filled spent lime roll-off. The composite spent lime sample is analyzed and, if approved by the landfill, is released for disposal. An approved waste hauling company is contracted to haul the spent lime to an approved landfill for disposal

C. As required by 15A NCAC 13B .1207 (3) sections (f) through (k), composite samples are obtained for the ash and spent lime on a pre-determined schedule. A representative sample of about 1 kg (2.2 lbs) is collected for each roll-off container per the GSK sampling procedure. A forward-looking sample analysis protocol is used to project the analysis of the waste for a six month time period into the future. Samples are collected in closed containers, thoroughly mixed, and reduced to a representative composite sample. All samples are obtained from the ash and spent lime collection systems and managed as follows.

D. Scheduled Sampling Period: GSK analyzes and holds one random ash roll-off container and one random spent lime roll-off container every 6 months to check for TCLP constituents, free liquids, and pH. If all constituents are acceptable and approved by the landfill, GSK commences regular shipping of the waste to UPE for the next 6 months until the next scheduled sampling period. The ash and spent lime analysis is scheduled every six months, once in April, and once in October.

E. All samples are composites and representative of the entire roll-off. All containers being sampled are held until analysis is completed and approved. All containers with unacceptable results will be re-sampled and if still unacceptable will be shipped off-site as hazardous waste. To ensure that the constituent with unacceptable result is not an ongoing issue, the next 4 roll-off containers after the unacceptable container will be sampled. Each sampled roll-off is held during analysis and submitted for approval before shipment. Four acceptable containers in a row will allow GSK to commence the regular shipping of the waste stream to the landfill.

F. Representative samples will be analyzed per RCRA SW-846 for TCLP Metals, TCLP Volitiles, TSLP Semi-volitiles, paint filter free liquid and pH according to 15A NCAC 13B .0103(d) "Procedure and Criteria For Waste Determination".

G. A log documents the ash sampling including the date and time each sample was taken; the date, time and identification number each composite sample; and the results of analysis with laboratory identification. Exhibit # 24 depicts the sample log and Exhibit # 25 represents the composite log that will be used for the facilities.

## VII. Operator Training Program

All GlaxoSmithKline incinerator operators are placed into a training program that includes the instrumentation, equipment operation and practices based on SOP's developed by operators and management using the manufacturers best practices for operations and maintenance of the equipment. All operators are trained to understand the basic principles and operations of each of the systems that contribute to the incinerator operations. The operators must learn the operations of the systems from either a manufacturer’s representative or an experienced operator.

The incinerator is subject to the 40 CFR Part 62 requirements for Commercial and Industrial Solid Waste Incinerators (CISWI rule).The CISWI training program consists of the following components (based on the unit):

Incineration technology and principles

Incinerator Unit specific operations procedures
Waste Feed System
Off-gas control systems and principles - Interel
Continuous Monitoring Devices and systems
Permit and operating limits
Lime Delivery Systems and operations
Ash Handling System and Procedure
Forklift Operator Training

**VIII. Contingency Plan Note: 1. This section was updated in July 2007 to reflect agreements with the NC Solid Waste Section concerning the ASH SAMPLING PLAN. Note 2. This section was revised in July 2009 to reflect updated agreements with the NC Solid Waste Section and Republic Services UPE landfill staff concerning the ASH SAMPLING PLAN.**

The GlaxoSmithKline South Campus incineration facilities were constructed to provide support to Research and Development, maintenance, site services and other Solid Waste generators in the onsite management of Solid Wastes. These facilities, in conjunction with other methods of waste management like recycling and reduction, were designed to provide GlaxoSmithKline with the opportunity to reduce the volume and hazards of wastes that would typically be managed in a landfill.

Current methods of waste management include recycling paper, cardboard, fluorescent tubes, food wastes, tin, and, aluminum. Other candidate waste streams are under evaluation for recycling. Those wastes that are not candidates for a recycling program, including, medical wastes, bedding, animal carcasses, pharmaceutical product returns or rejects are treated onsite for waste volume and hazard reduction.

The ASH SAMPLING PLAN in section VI (Medical Waste Management) of this application (above) describes the process for ash and spent lime management. This plan (in section VI.2.E.) describes the contingency plans in case the ash or spent lime is analyzed to contain constituents that are TCLP hazards waste.

An approval for disposal of ash and spent lime treatment residues is currently in place for the Republic Services Upper Piedmont Environmental Landfill in Rougemont, NC. Ash is shipped directly to the landfill facility in an open top roll-off container with a tarp cover. Spent lime is shipped directly to the landfill in an enclosed roll-off container.

The Spill Response plan in section IX (Medical Waste Management Plan) of this application (below) describes the process for clean-up of incidental spills of Regulated Medical Waste. Spills of ash or spent lime are not Regulated Medical Waste. Ash and Spent lime spills are cleaned up using brooms and vacuum cleaners with the resulting material being discarded in the ash roll-off container.

In the event that the wastes generated onsite cannot be managed in the GlaxoSmithKline RTP incineration facilities and exceeds the storage capacity at the facilities, GSK management will arrange for the incineration of pharmaceutical returns and biomedical wastes at an approved solid waste facility.

In the event that a load of trash or animal bedding cannot be delivered to the GlaxoSmithKline RTP facility for incineration, the contract hauling company will be directed by GSK management to deliver the load to an approved landfill or to an approved commercial incinerator.

GSK management capable of implementing the Contingency plan for disposal includes the Environmental Heath and Safety managers.

**Exhibit # 23**

## IX. Medical Waste Management Plan

Scope

All personnel involved in the packaging, labeling, loading and preparations of shipping papers of Regulated Medical Waste for inter-facility transport are required to adhere to the following procedures.

Procedure

Regulated Medical Wastes consist of paper, plastic, glass, cultures, bodily fluids, blood, media, sharps, animal wastes, carcasses and laboratory equipment contaminated with biological agents (< BSL 3) or pathogens. These wastes are generated in GlaxoSmithKline laboratories and animal management facilities and are managed for disposal by the Environmental Health and Safety group. Materials exposed to BSL 3 or above are treated to remove or reduce the hazard prior to removal from the lab for ultimate disposal by incineration in accordance with 15A NCAC 13B.1207(3).

Packaging

The Environmental Health and Safety Group provides generators with boxes marked with the Universal Biohazard Symbol and the words "Biohazardous Waste". In addition, each box is accompanied by a 3 mil. polypropylene bag meeting 15A NCAC 13B.1204(a)(1) and marked with the Biohazard symbol and the words "Infectious Waste". These materials constitute the minimum packaging to be used by the laboratory for packaging Regulated Medical Wastes.

Boxes must be securely taped on the bottom prior to loading the box with wastes. Inner plastic liner must be tied or taped securely prior to removal from the lab. Individual sharps containers may be removed as waste if the top is secured and the Universal Biohazard Symbol and the words "Biohazard" are present on the container.

Labeling

Boxes for inter-facility transport are labeled with the generating facility address, phone number and contact name; transporter address, phone number and contact name; and, receiving facility address, phone number and contact name. The box is dated prior to shipment.

Loading

Accumulated Regulated Medical Waste is inspected for signs of leakage or spillage prior to loading for transport. Boxes are not stacked greater than three high. Boxes are secured using straps or retainers to prevent shifting during transport. Shipping papers are prepared indicating the appropriate DOT shipping name, generator name, receiving facility name, transporter and the piece count loaded.

**Exhibit # 23 Continued**

Unloading

Containers are inspected for signs of leakage or spillage during transport. A piece count is taken and the shipping paper is reconciled and signed. Copies of the shipping paper are maintained at the receiving facility and one copy is returned to the generator. Copies are retained for three years.

Spill Response

In the event of leakage or spillage involving Regulated Medical Waste or residues during storage or transport, spill remediation must be completed to treat and remove the spilled/leaked materials. From a distance observe the extent of the spill and the nature of the materials involved. Spray a mist of 10% Clorox to cover the spilled materials from the outside of the spill toward the center. Allow 20 minutes for aerosols to settle before attempting to collect the waste. Don latex gloves under neoprene or butyl gloves and a face-shield or safety glasses. Use a broom and dust-pan to collect spilled solids and a mop to collect spilled liquids. Package solids in another Biohazard Waste box. Mop the area with a weak solution of Clorox and dispose or liquids to the sanitary sewer. Either properly dispose of the contaminated broom, dust pan, mop, and mop bucket, or properly decontaminate with 10 % bleach for 20 minutes after use in spill response. For liquids spilled during transport, saturate the area with Clorox spray and allow 20 minutes for aerosols to settle. Absorb the free liquids and cover the remaining wetted area with Clorox.

END OF APPLICATION

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